

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|---|--|
| Applicant's or agent's file reference 6395 - 68278 - 02 | FOR FURTHER ACTION <div style="float: right; font-size: small;">see Form PCT/ISA/220 as well as, where applicable, item 5 below.</div> | |
| International application No. PCT/US2005/011086 | International filing date (day/month/year) 01/04/2005 | (Earliest) Priority Date (day/month/year) 02/04/2004 |
| Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA ... | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 4b
☐ as suggested by the applicant
☒ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

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International application No.
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Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **58**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy: a method of using an aerosolizing device for administering an aerosolized agent to a patient.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-25

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-25

Claims 1-25 essentially define an aerosolizing element comprising a movable element being capable of moving in response to an external force.

2. claims: 26-41

Claims 26-41 essentially define an aerosolizing device including a disposable aerosolizing element being removable from the housing of the aerosolizing device.

3. claims: 42-57

Claims 42-57 essentially define an aerosolizing device including a disposable aerosolizing element, wherein the element prevents the agent to be expelled from contacting an actuator.

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Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Methods and systems for aerosol delivery of agents to a patient are described herein. The present system can be used to administer various types of agents, such as a vaccine or other types of pharmaceutical substances. Certain embodiments of the present system utilize an (18) actuator coupled to a disposable aerosolizing element (16) that aerosolizes an agent for delivery to a patient when acted upon by the actuator. The aerosolizing element prevents the agent from contacting the actuator and other non-disposable components of the system so that little or no cleaning or maintenance is required. The present system also can include an aerosolization rate monitor that monitors the rate at which an agent is being aerosolized and provides feedback to the user to ensure that the proper dose is being administered.

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A. CLASSIFICATION OF SUBJECT MATTER
A61M11/00 B05B17/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M B05B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|---------------------------------|
| X | EP 1 149 602 A (MICROFLOW ENGINEERING SA) 31 October 2001 (2001-10-31) | 1-11, 15-25 |
| Y | the whole document | 12-14 |
| X | US 5 709 202 A (LLOYD ET AL) 20 January 1998 (1998-01-20) | 1-3, 5-10, 16, 17, 24, 25 |
| Y | column 28, line 52 - column 32, line 40; figures 6-8, 10 | 13, 14 |
| X | US 2002/124852 A1 (GONDA IGOR ET AL) 12 September 2002 (2002-09-12) | 1-6, 12-14, 16, 17 |
| Y | paragraphs [0259] - [0261]; figure 13 | 12-14 |
| | ----- -/-- | |

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

28 November 2005

Date of mailing of the international search report

08.03.2006

Name and mailing address of the ISA/

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Borowski, A

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International application No
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| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|---|-----------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| A | WO 02/074372 A (THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS REPRESENTED BY THE S) 26 September 2002 (2002-09-26) the whole document ----- | 1-25 |
| A | WO 00/58022 A (LIPOSOL LTD; FICHMAN, MATITIAU; GOLDMAN, BORIS) 5 October 2000 (2000-10-05) the whole document ----- | 1-25 |
| A | US 2003/164169 A1 (STANGL ROLAND ET AL) 4 September 2003 (2003-09-04) figures 4a-6c ----- | 1 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2005/011086

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|----|---------------------|----------------------------|---------------------|
| EP 1149602 | A | 31-10-2001 | NONE | |
| US 5709202 | A | 20-01-1998 | US 5497763 A | 12-03-1996 |
| US 2002124852 | A1 | 12-09-2002 | US 2002046750 A1 | 25-04-2002 |
| WO 02074372 | A | 26-09-2002 | AT 299729 T | 15-08-2005 |
| | | | CA 2439766 A1 | 26-09-2002 |
| | | | DE 60205093 D1 | 25-08-2005 |
| | | | EP 1370318 A2 | 17-12-2003 |
| WO 0058022 | A | 05-10-2000 | AU 3321900 A | 16-10-2000 |
| US 2003164169 | A1 | 04-09-2003 | DE 10040528 A1 | 28-02-2002 |
| | | | WO 0213896 A1 | 21-02-2002 |